# **Complete Summary**

### **GUIDELINE TITLE**

Urinary incontinence in women.

# **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Urinary incontinence in women. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Jun. 13 p. (ACOG practice bulletin; no. 63). [70 references]

## **GUIDELINE STATUS**

This is the current release of the guideline.

# \*\* REGULATORY ALERT \*\*

## FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

May 2, 2007, Antidepressant drugs: Update to the existing black box warning
on the prescribing information on all antidepressant medications to include
warnings about the increased risks of suicidal thinking and behavior in young
adults ages 18 to 24 years old during the first one to two months of
treatment.

# **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\*

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

**DISCLAIMER** 

# **SCOPE**

# **DISEASE/CONDITION(S)**

Urinary incontinence

### **GUIDELINE CATEGORY**

Diagnosis Management Treatment

### **CLINICAL SPECIALTY**

Family Practice
Internal Medicine
Obstetrics and Gynecology
Surgery
Urology

## **INTENDED USERS**

**Physicians** 

# **GUIDELINE OBJECTIVE(S)**

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To consider the best available evidence for evaluating and treating urinary incontinence in women

### **TARGET POPULATION**

Women with urinary incontinence

# INTERVENTIONS AND PRACTICES CONSIDERED

# **Diagnosis**

- 1. Medical and medication history
- 2. Voiding diary
- 3. Physical examination, including gynecologic and lower neurologic examinations
- 4. Measurement of urethral mobility
- 5. Urinalysis
- 6. Blood tests (blood urea nitrogen, creatinine, glucose, calcium) for suspected renal compromise
- 7. Urine cytology, in limited cases
- 8. Voiding assessment of urinary bladder (transurethral catheterization, ultrasound)

- 9. Urodynamic tests (cystometry, uroflowmetry, postvoid residual urine volume, pressure flow voiding study, electromyography)
- 10. Cystourethroscopy
- 11. Urethral pressure profilometry and leak point pressure measurement not recommended

# Management

- 1. Absorbent products
- 2. Behavioral modification (lifestyle intervention, scheduled or prompted voiding, bladder training, pelvic muscle rehabilitation)
- 3. Medical management (estrogen, anticholinergic agents [oxybutynin chloride, tolterodine], tricyclic antidepressants [imipramine], musculotropic drugs)
- 4. Surgical treatments (retropubic laparoscopic or open Burch colposuspension and sling procedures, tension-free vaginal tape procedure, anterior colporrhaphy, pubovaginal fascial bladder neck sling)
- 5. Injection of bulking agents (collagen, carbon-coated beads, fat) as second-line therapy or for women ineligible for surgery
- 6. Pessaries
- 7. Hysterectomy (for concomitant uterine prolapse or specific uterine pathology)
- 8. Paravaginal defect repair (not recommended as primary treatment of urodynamic stress incontinence)

# **MAJOR OUTCOMES CONSIDERED**

- Cure rate
- Relapse rate
- Duration of improvement
- Quality of life
- Patient satisfaction
- Complication rates of surgery

# **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

# **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and February 2005. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the

American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

## **NUMBER OF SOURCE DOCUMENTS**

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

# RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

# **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of" field regarding Grade C recommendations.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

**Level A** — Recommendations are based on good and consistent scientific evidence.

**Level B** — Recommendations are based on limited or inconsistent scientific evidence.

**Level C** — Recommendations are based primarily on consensus and expert opinion.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

# The following recommendations are based on good and consistent scientific evidence (Level A):

 Behavioral therapy, including bladder training and prompted voiding, improves symptoms of urge and mixed incontinence and can be recommended as a noninvasive treatment in many women.

- Pelvic floor training appears to be an effective treatment for adult women with stress and mixed incontinence and can be recommended as a noninvasive treatment for many women.
- Pharmacologic agents, especially oxybutynin and tolterodine, may have a small beneficial effect on improving symptoms of detrusor overactivity in women.

# The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Cystometric testing is not required in the routine or basic evaluation of urinary incontinence.
- Bulking agents are a relatively noninvasive method of treatment for stress incontinence and can be used in women for whom any form of operative treatment is contraindicated.
- Long-term data suggest that Burch colposuspension and sling procedures have similar objective cure rates; therefore, selection of treatment should be based on patient characteristics and the surgeon's experience.
- The combination of a hysterectomy and a Burch colposuspension does not result in higher continence rates than a Burch procedure alone.
- Tension-free vaginal tape and open Burch colposuspension have similar success rates.
- Anterior colporrhaphy, needle urethropexy, and paravaginal defect repair have lower cure rates for stress incontinence than Burch colposuspension.

# The following recommendations are based primarily on consensus and expert opinion (Level C):

- After the basic evaluation of urinary incontinence, simple cystometry is appropriate for detecting abnormalities of detrusor compliance and contractibility, measuring postvoid residual volume, and determining capacity.
- Patients with urinary incontinence should undergo a basic evaluation that includes a history, physical examination, measurement of postvoid residual volume, and urinalysis.

## Definitions:

## **Grades of Evidence**

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.
- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

**III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

## **Levels of Recommendations**

**Level A** — Recommendations are based on good and consistent scientific evidence.

**Level B** — Recommendations are based on limited or inconsistent scientific evidence.

**Level C** — Recommendations are based primarily on consensus and expert opinion.

# **CLINICAL ALGORITHM(S)**

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Appropriate evaluation and management of patients with urinary incontinence

## **POTENTIAL HARMS**

### **Medical Intervention**

- The response to pharmacologic treatment often is unpredictable, and side effects are common with effective doses.
- The most typical side effect of anticholinergic therapy is dry mouth; other side effects most frequently reported were blurred vision, constipation, nausea, dizziness, and headache.

# **Surgical Intervention**

 Intraoperative or immediate postoperative complications of surgery for stress incontinence include direct surgical injury to the lower urinary tract, hemorrhage, bowel injury, wound complications, retention, and urinary tract infection. Gynecologic surgeons may perform cystoscopy during or after retropubic and sling procedures to verify ureteral patency and the absence of sutures or sling material in the bladder. Most of the chronic complications

- after Burch colposuspension and sling procedures relate to voiding dysfunction and urge symptoms (see Table 2 in the original guideline document).
- Retropubic suspensions and sling procedures are associated with slightly higher complication rates, including longer convalescence and postoperative voiding dysfunction.
- A multicenter randomized trial found no difference between Burch colposuspension and tension-free vaginal tape procedures, with objective cure rates for urodynamic stress incontinence of 57% and 66%, respectively. Bladder injury was more common during the tension-free vaginal tape procedure (P = .013); delayed voiding, operation time (P < .001), and return to normal activity (P < .001) were all longer after colposuspension.</li>

# **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

# **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

## **IMPLEMENTATION TOOLS**

Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Getting Better Living with Illness

## **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

American College of Obstetricians and Gynecologists (ACOG). Urinary incontinence in women. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Jun. 13 p. (ACOG practice bulletin; no. 63). [70 references]

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## **DATE RELEASED**

2005 Jun

# **GUIDELINE DEVELOPER(S)**

American College of Obstetricians and Gynecologists - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

American College of Obstetricians and Gynecologists (ACOG)

## **GUIDELINE COMMITTEE**

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the ACOG Web site.

## **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

The following is available:

• Urinary incontinence. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2005.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site.</u>

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the ACOG Web site.

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## **NGC STATUS**

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